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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,188	03/24/2004	Richard Deslauriers	22469-005001	4577

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EXAMINER	
WELTER, RACHAEL E	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
01/15/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/808,188	DESLAURIERS ET AL.	
	Examiner	Art Unit	
	RACHAEL E. WELTER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *397-419* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *397-419* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :3/24/04, 8/19/04, 10/19/04, 2/11/05, 2/16/06, 3/21/06, 3/28/06, 2/15/07

DETAILED ACTION

Acknowledgements

The examiner acknowledges applicant's response on 9/1/09 to the notice regarding a non-compliant amendment confirming that the prior restriction requirement/election of species is no longer applicable.

Claim Status

Claims 397-419 are pending. Claims 1-396 are cancelled.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on February 15, 2007, March 28, 2006, March 21, 2006, and February 16, 2006, February 11, 2005, October 19, 2004, August, 19, 2004, March 24, 2004, and January 5, 2010 were in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. Accordingly, the information disclosure statements were considered by the examiner. A signed copy of forms 1449 are enclosed herewith. Additionally, the examiner notes that references MU 7900158-OU, MU 7900159-9U, and Salvador Claro Neto et al were not considered because no English translations or English abstracts of the references were provided.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is

requested in correcting any errors of which applicant may become aware in the specification.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original non-provisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/395,001 (filing date: 3/24/03), which claims benefit of provisional Application No. 60/366335 (filing date: 3/22/02), fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

Independent claims 397 and 409 of the present application are drawn to administering a castor-oil based polyurethane bone scaffold composition with a final cured state having an average pore size of form about 5 microns to about 500 microns and a compressive strength of at least about 50 MPa. However, the prior-filed

application (10/395,001) does not have support for pore size and the compressive strength of the composition. Although, applicant does have support in the prior-filed application for independent claim 413, dependent claims 417-419 and part of claim 416 fail to have support. In the prior-filed application, applicant does not mention filler materials, such as poly methyl methacrylate, glass-ionomer, poly ether ether ketone, calcium sulfate, demineralized bone, allograft bone, autogenous bone, and beta tricalcium phosphate. Additionally, applicant does not teach the addition of radiotransparent substances and radiopaque substances to the bone scaffold composition in the prior-filed application. Furthermore, applicant does not have support for any of the claims in the provisional application (60/366335).

As such, claims 413-415 and partially claim 416 will be entitled to the benefit of the priority date of Application No. 10/395,001. No claims will be given the priority date of provisional Application No. 60/366335 and claims 397-412, 417-419, and partially claim 416 will not be given the priority date of Application No. 10/395,001. If applicant disagrees, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the earlier priority applications. Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 397-408 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 397, 402, 404, and 405 recite the limitation, "...at least about." "At least" is a minima and all possible values above 50 MPa, above 20 minutes, above 40 MPa, and above 1,500 MPa are encompassed respectively. "About" indicates a range centered on the recited value. In this case, "about" indicates values both above and below the quantitative values cited. Therefore, what values are included in the range "at least about 50MPa," "at least about 20 minutes," "at least about 40 MPa," and "at least about 1,500 MPa" cannot be determined.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 413-416 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio et al (Rev. Bras. Ortop., Vol. 32, No. 10, 1997) in view of Arnett (US Patent No. 6,506,217).

Ignacio et al teach the use of polyurethane derived from castor oil with calcium carbonate to fill segmental diaphyseal bone defects in radii of rabbits (pg. 1, column 2). According to Ignacio et al, moldable polyurethane was implanted inside of the bone defect while still pasty, with careful adaptation to the bone stumps (pg. 3, column 1). About 10 to 15 minutes were necessary in order for the polyurethane to become completely polymerized and rigid.

Ignacio et al do not teach the step of manipulating said bone scaffold composition in situ using external pressure applied to the skin of the patient after administration of the composition.

Arnett teaches the implantation of a bone filler and bone conforming material via surgery, wherein after surgery, the surgeon can continue to adjust or modify the contours of the patient body in the areas with the bone conforming material by applying pressure to the skin, muscle, and other tissue overlaying the implant to thereby mold or shape the implanted bone conforming material (column 2, lines 24-34).

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to apply external pressure to the skin of the rabbits after implantation of the moldable polyurethane of Ignacio et al. One would have been motivated to do so since Arnett suggests that it is conventional after implanting bone filler to mold or shape the implanted material externally by applying pressure to the skin

overlapping the bone conforming material. Additionally, it would have been obvious to further shape the bone conforming material in such a way because it is non-invasive and enables the surgeon to improve aesthetic results.

Claims 417-418 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio et al (Rev. Bras. Ortop., Vol. 32, No. 10, 1997) in view of Arnett (US Patent No. 6,506,217) as applied to claims 413-416 above and in further view of Nathan et al (US Patent No. 7,030,127).

The disclosures of Ignacio et al and Arnett are discussed above.

Ignacio et al and Arnett do not teach a composition comprising a filler material made of beta tricalcium phosphate, demineralized bone, allograft bone, or autogenous bone.

Nathan et al teach that bone replacement material can be made of fillers: beta-tricalcium phosphate, calcium phosphate, calcium carbonate, and demineralized bone (column 8, lines 6-21).

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to combine the teachings above and utilize the fillers of Nathan et al or Ignacio et al. One would have been motivated to do so since Nathan et al teach that the instant fillers (i.e., beta tricalcium phosphate and demineralized bone) and Ignacio's filler (calcium carbonate) are both useful components in bone replacement material. Thus, one would have been motivated to substitute the instant bone fillers (beta tricalcium phosphate and demineralized bone) into the composition of Ignacio et al

with an expectation of similar results since Nathan et al teach their equivalency with calcium carbonate.

Claim 419 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio et al (Rev. Bras. Ortop., Vol. 32, No. 10, 1997) in view of Arnett (US Patent No. 6,506,217) as applied to claims 413-416 above and in further view of Nakabayashi et al (US Patent No. 5,264,215).

The disclosures of Ignacio et al and Arnett are discussed above.

Ignacio et al and Arnett do not teach the addition of radiotransparent substances or radiopaque substances.

Nakabayashi et al teach a bone cement composition and teach the addition of barium sulfate X-ray contrast medium (column 6, lines 7-10).

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to add a radiopaque substance to the composition of Ignacio et al. One would have been motivated to so since Nakabayashi et al teach that it is conventional to add such substances in orthopedic formulations. Furthermore, one would have been motivated to do so if the physician desired to determine the condition or location of Ignacio's composition as well visualize the repair of the bone through the use of X-ray photographs.

Claims 409-410 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adhikari et al (WO 2004/009227) in view of Arnett (US Patent No. 6,506,217).

Adhikari et al teach a bone-growth promoting composition, comprising: an osteoconductive polyurethane composition having in its cured state an average pore size of 150-300 microns (at least 1.5 microns) and a compressive strength of 0.05-80 MPa (a compressive strength consistent for use in bone repair), wherein the polyurethane composition is suitable for use *in vivo* (abstract; pg. 8, lines 11-17). In one example, the compressive strength is 61.9 MPa (at least about 40 MPa; at least about 50 MPa) (see Example 15). According to Adhikari et al, such compositions can be cured ex-vivo and then implanted using invasive medical procedures, or cure in-vivo, after insertion by non-invasive medical methods such as by arthroscope (pg. 7, lines The polyurethane is made by the process of combining a polyol, an isocyanate, and water (pg. 5, line 31 to pg. 6, line 16; Example 11). The amount of water added in one example is 0.3% by weight of the composition (see Example 11; calculated from 0.008/(2.20 + 0.8 + 0.008) x 100%). Polyols to be used include sucrose (a naturally-occurring polyol) and pentaerythritol (a synthetic polyol). Filler materials such as calcium phosphate may be added (pg. 10, lines 3-11). Calcium phosphate may be present in about 4 wt% (from about 0.01% to about 30% by weight of the composition) (pg. 22, lines 15-16).

Adhikari et al do not teach the step of manipulating said bone scaffold composition in situ using external pressure applied to the skin of the patient after administration of the composition.

Arnett teaches the implantation of a bone filler and bone conforming material via surgery, wherein after surgery, the surgeon can continue to adjust or modify the

contours of the patient body in the areas with the bone conforming material by applying pressure to the skin, muscle, and other tissue overlaying the implant to thereby mold or shape the implanted bone conforming material (column 2, lines 24-34).

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to apply external pressure to the skin of patients after implantation of the polyurethane composition of Adhikari et al. One would have been motivated to do so since Arnett suggests that it is conventional after implanting bone filler to mold or shape the implanted material externally by applying pressure to the skin overlapping the bone conforming material. Additionally, it would have been obvious to further shape the bone conforming material in such a way because it is non-invasive and enables the surgeon to improve aesthetic results.

Claims 397-408 and 412 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adhikari et al (WO 2004/009227) in view of Arnett (US Patent No. 6,506,217) and Sandvig et al (US Patent No. 5,800,899).

Adhikari et al teach a bone-growth promoting composition, comprising: an osteoconductive polyurethane composition having in its cured state an average pore size of 150-300 microns (at least 1.5 microns) and a compressive strength of 0.05-80 MPa (a compressive strength consistent for use in bone repair), wherein the polyurethane composition is suitable for use *in vivo* (abstract; pg. 8, lines 11-17). In one example, the compressive strength is 61.9 MPa (at least about 40 MPa; at least about 50 MPa) (see Example 15). According to Adhikari et al, such compositions can be

cured ex-vivo and then implanted using invasive medical procedures, or cure in-vivo after insertion by non-invasive medical methods such as by arthroscope (pg. 7, lines The polyurethane is made by the process of combining a polyol, an isocyanate, and water (pg. 5, line 31 to pg. 6, line 16; Example 11). The amount of water added in one example is 0.3% by weight of the composition (see Example 11; calculated from 0.008/(2.20 + 0.8 + 0.008) x 100%). Polyols to be used include sucrose (a naturally-occurring polyol) and pentaerythritol (a synthetic polyol). Filler materials such as calcium phosphate may be added (pg. 10, lines 3-11). Calcium phosphate may be present in about 4 wt% (from about 0.01% to about 30% by weight of the composition) (pg. 22, lines 15-16).

Adhikari et al do not teach the step of manipulating said bone scaffold composition in situ using external pressure applied to the skin of the patient after administration of the composition.

Arnett teaches the implantation of a bone filler and bone conforming material via surgery, wherein after surgery, the surgeon can continue to adjust or modify the contours of the patient body in the areas with the bone conforming material by applying pressure to the skin, muscle, and other tissue overlaying the implant to thereby mold or shape the implanted bone conforming material (column 2, lines 24-34).

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to apply external pressure to the skin of patients after implantation of the polyurethane composition of Adhikari et al. One would have been motivated to do so since Arnett suggests that it is conventional after implanting bone

filler to mold or shape the implanted material externally by applying pressure to the skin overlapping the bone conforming material. Additionally, it would have been obvious to further shape the bone conforming material in such a way because it is non-invasive and enables the surgeon to improve aesthetic results.

Furthermore, Adhikari et al do not teach a castor-oil based polyurethane composition. However, Adhikari et al do teach that its polyols that make up the polyurethane composition are low molecular weight and have two and preferably three or more functional groups that react with isocyanate groups to form urethane or urea groups (see pg. 13, lines 5-27).

Sandvig et al teach orthopedic casting material and that Caspol 5001 (a castor-oil based polyol having three or more functional groups) is known in the art to react with isocyanates to form polyurethanes in such material (see abstract; col 4, lines 47-53).

Therefore, it would have been obvious to one of ordinary skill at the time the invention was made to use a castor-oil base polyurethane, such as Caspol 5001 as the polyol of Adhikari et al. One would have been motivated to do so since this compound meets the structural and chemical requirements of Adhikari and such polyols are known in the art for the purpose of making polyurethanes with orthopedic applications.

Regarding claims 402-405 and 407-408, which are directed to additional properties of the composition, the examiner notes that although Adhikari et al do explicitly teach these properties, the examiner has a reasonable basis to believe that the properties claimed in the present invention would be expected in the composition of Adhikari et al based on the substantially identical process using identical components.

""[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999).* Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)."* Burden is on applicant to prove otherwise.

Claim 411 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adhikari et al (WO 2004/009227) in view of Arnett (US Patent No. 6,506,217) as applied to claims 409-410 above and in further view of Nathan et al (US Patent No. 7,030,127).

The disclosures of Adhikari et al and Arnett are discussed above.

Adhikari et al and Arnett do not teach a composition comprising a filler material made of calcium carbonate. Rather, Adhikari et al teach that its composition can comprise calcium phosphate.

Nathan et al teach that bone replacement material can be made of fillers: beta-tricalcium phosphate, calcium phosphate, calcium carbonate, and demineralized bone (column 8, lines 6-21).

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to combine the teachings above and utilize the fillers of Nathan et al or Adhikari et al. One would have been motivated to do so since Nathan et al teach that the instant filler (i.e., calcium carbonate) and Adhikari's filler (calcium

phosphate) are both useful components in bone replacement material. Thus, one would have been motivated to substitute the instant bone filler into the composition of Adhikari et al with an expectation of similar results since Nathan et al teach its equivalency with calcium phosphate.

Conclusion

Claims 397-419 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL E. WELTER whose telephone number is (571) 270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW
/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
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